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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F-0730]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to change the density specifications for ethylene-maleic anhydride copolymers intended for use in contact with food. This action is in response to a petition filed by Keller and Heckman LLP.

DATES: The regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 8, 1998 (63 FR 47503), FDA announced that a food additive petition (FAP 8B4623) had been filed by Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR

177.1520), to change the the density specifications from “0.92–0.94” to “0.92 or greater” for ethylene-maleic anhydride copolymers intended for use in contact with food.

The September 8, 1998, filing notice for the petition stated that the action resulting from the petition qualified for a categorical exclusion under 21 CFR 25.32(i). Upon further review, the agency determined that such a categorical exclusion is not appropriate for this action because the additive is expected to be present in the finished food-contact article at a level greater than 5 percent by weight. Consequently, the agency considered the environmental effects of this action.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency has determined that the petitioner has adequately demonstrated that ethylene-maleic anhydride copolymers with a density specification of “0.92 or greater” in place of “0.92–0.94”, conform to the identity and specifications under § 177.1520(c), item 6 for ethylene-maleic anhydride copolymers. Thus, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 177.1520 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact persons listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency’s finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before *(insert date 30 days after date of publication in the **Federal Register**)*, file with the Dockets Management Branch (address above) written objection thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

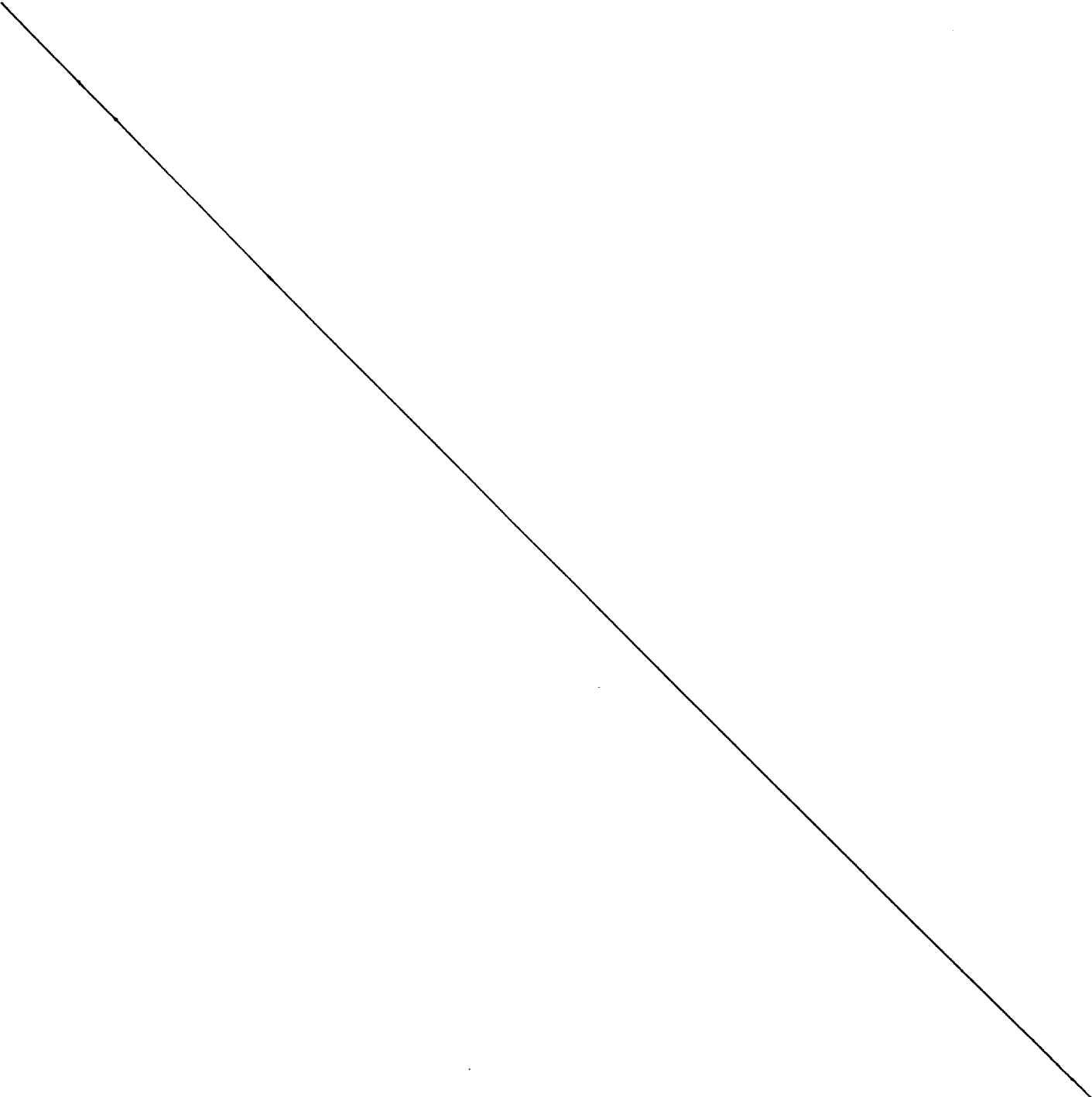
Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1520 is amended in the table in paragraph (c) by revising item “6.” under the heading “Density” to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(c) * * *



Olefin Polymers	Density	Melting Point (MP) or softening point (SP) (Degrees Centigrade)	Maximum extractable fraction (expressed as percent by weight of the polymer) in N-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of the polymer) in xylene at specified temperatures
6. Ethylene-maleic anhydride copolymers described in paragraph (a)(6) of this section for use as the adhesive component in multilaminate structures, or as the sealant layer in flexible packaging, in contact with food at temperatures not exceeding 49 °C (120 °F)	0.92 or greater		1.36 pct at 50 °C.	2.28 pct at 25 °C

*with
Pentane
✓
✓
OFR*

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Dated: 5/5/99

May 5, 1999

L. Robert Lake

L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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